COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 26-IV-2004
C(2004) 1721

NOT FOR PUBLICATION

COMMISSION DECISION

of 26-IV-2004

granting marketing authorisation for the medicinal product for human use "Velcade - bortezomib" under Council Regulation (EEC) No 2309/93

(Text with EEA relevance)

ONLY THE ENGLISH TEXT IS AUTHENTIC

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1], as amended by Commission Regulation (EC) No 649/98[2], and in particular Article 10(2) thereof,

Having regard to the application submitted by Millenium Pharmaceuticals, Ltd, on 24 February 2003, under Article 4(1) of Regulation (EEC) No 2309/93,

Having regard to the opinion of the European Agency for the Evaluation of Medicinal Products, formulated by the Committee for Proprietary Medicinal Products on 21 January 2004,

Whereas:

(1) The medicinal product "Velcade - bortezomib" complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3] as amended by Directive 2002/98/EC[4] and by Directive 2003/63/EC[5].

(2) Following consultations with the applicant, the Committee for Proprietary Medicinal Products has pointed out the existence, in this instance, of exceptional circumstances which justify making the requested authorisation conditional on the fulfilment of certain specific obligations.

[1] OJ L 214, 24. 8. 1993, p. 1.
[2] OJ L 88, 24.3.1998, p. 7.
[3] OJ L 311, 28.11.2001, p. 67.
[4] OJ L 33, 8.2.2003, p. 30.
[5] OJ L 159, 27.6.2003, p. 46.

(3) Marketing authorisation should therefore be granted under the provisions for exceptional circumstances laid down in Article 13(2) of Regulation (EEC) No 2309/93.

(4) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorization referred to in Article 3 of Regulation (EEC) No 2309/93 is hereby granted in respect of the medicinal product, "Velcade - bortezomib" whose characteristics are summarized in Annex I hereto. This medicinal product shall be entered in the Community Register of Medicinal Products under the number:

EU/1/04/274/001 VELCADE-3.5 mg-Powder for solution for injection-Intravenous use-Vial (glass)-1 vial

Article 2

The marketing authorisation referred to in Article 1 shall be subject to specific obligations which are summarised in Annex II and which will be re-evaluated annually.

Article 3

The labelling and package leaflet concerning the orphan medicinal product referred to in Article 1 shall conform to Annex III.

Article 4

The period of validity of the authorization issued shall be five years from the date of notification of this Decision. It shall be renewable under the conditions laid down in Article 13(1) of Regulation (EEC) No 2309/93.

Article 5

This Decision is addressed to Millenium Pharmaceuticals, Ltd, Building 3, Chiswick Park, 566 Chiswick High Road, Chiswick, London, W4 5YA United Kingdom.

Done at Brussels, 26-IV-2004

For the Commission
Erkki LIIKANEN
Member of the Commission